

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/014767

International filing date (day/month/year)
21.12.2004

Priority date (day/month/year)
23.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/00

Applicant
GLAXO GROUP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/014767

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the *international application* in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/014767

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-14
	No: Claims	
Inventive step (IS)	Yes: Claims	1-14
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V.

- 1 Reference is made to the following documents:
D1 : WO 01/74247 A (IEP PHARMACEUTICAL DEVICES INC) 11 October 2001
(2001-10-11)
D2 : WO 94/09700 A (HOOD LABORATORIES; BIOMECHANICS INC;
FREDBERG, JEFFREY; GLASS, GARY; L) 11 May 1994 (1994-05-11)
2. The present application relates to a method of predicting the deposition of inhaled particles in the throat of a patient. This may be helpful in the design and development of inhalers and improve their performance.
Predicting the deposition on the basis of a physical parameter (such as e.g. the volume or cross-sectional area of the throat), wherein the physical parameter has been assessed by acoustic imaging, and wherein the physical parameter is used with a reference set for predicting the tendency of deposition is not hinted at in the prior art. In D1 the effect of airway structures on the oral inhalation of respiratory drugs, wherein the airway structures are images by MRI. D1 does not use this information for prediction of deposition.
D2 relates to acoustic imaging, but is not related to particle deposition in the throat. Consequently, the subject-matter of the present set of claims meets the requirements of Article 33 (2) and (3) PCT.

Re Item VIII.

1. Although claims 1 and 11 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
2. Present claims 2 and 3 are not clear. In particular, the method as defined in claim 1 relates to a method of predicting the tendency of inhaled particles and, therefore,

does not include the step of inhaling the particles or of the situation where the particles are inhaled. Consequently, it is not clear how claim 1 is restricted by imposing some restrictions to the inhaled particles (as in claims 2 and 3) if this inhalation or particles are not involved in the method of claim 1. Claims 2 and 3, should have been cancelled accordingly.

It is observed, that inhalation of particles (comprising medicament) as such, falls under therapeutical methods (see Article 34 (4) (a) (i) PCT and Rule 67.1 (iv) PCT).